

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date
13 October 2005 (13.10.2005)

PCT

(10) International Publication Number
WO 2005/094725 A1

(51) International Patent Classification⁷:

A61F 2/06

(21) International Application Number:

PCT/SG2004/000338

(22) International Filing Date: 15 October 2004 (15.10.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

200401735-6 31 March 2004 (31.03.2004) SG

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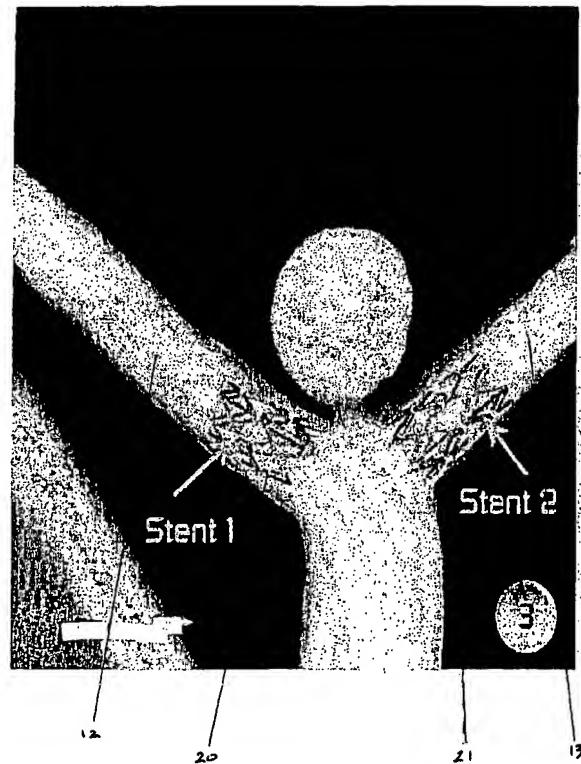
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

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(54) Title: A METHOD FOR TREATING ANEURYSMS



(57) Abstract: A Method For Treating Aneurysms A method for treating a bifurcation aneurysm, the aneurysm having an aneurysm neck, the method comprising positioning a first mechanically expandable device in a first bifurcation branch proximate to the aneurysm neck; positioning a second mechanically expandable device in a second bifurcation branch proximate to the aneurysm neck; and expanding the mechanically expandable devices to constrict the aneurysm neck such that blood circulation to the bifurcation aneurysm is reduced.

WO 2005/094725 A1



FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,
SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

Declaration under Rule 4.17:

— *of inventorship (Rule 4.17(iv)) for US only*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Title**A Method for Treating Aneurysms****Technical Field**

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The invention concerns a method for treating bifurcation or trifurcation aneurysms. In particular, the method is suitable for bifurcation or trifurcation aneurysms with wide aneurysm necks.

10 Background of the Invention

An aneurysm is a bulge or a weakening of a wall of an artery. An aneurysm usually occurs where one main blood vessel splits into two (bifurcation) or three smaller vessels (trifurcation). Bifurcation aneurysms account for approximately 35% of all 15 cases of intracranial hemorrhagic disease.

Aneurysms may burst and cause bleeding into a covering around the brain called the subarachnoid space. This is referred to as a subarachnoid hemorrhage.

Subarachnoid hemorrhage secondary to a ruptured aneurysm causes a severe

20 headache.

Therefore, there is a desire for minimally invasive, less traumatic methods to treat bifurcation and trifurcation aneurysms.

25 Summary of the Invention

In a first preferred aspect, there is provided a method for treating a bifurcation aneurysm, the aneurysm having an aneurysm neck, the method comprising:

positioning a first mechanically expandable device in a first bifurcation

30 branch proximate to the aneurysm neck;

positioning a second mechanically expandable device in a second bifurcation branch proximate to the aneurysm neck; and

expanding the mechanically expandable devices to constrict the aneurysm neck such that blood circulation to the bifurcation aneurysm is reduced.

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The aneurysm neck may be constricted such that blood circulation to the aneurysm is completely interrupted.

The mechanically expandable devices may be stents.

The stents may be mechanically expanded such that blood circulation to the

5 bifurcation aneurysm via the aneurysm neck may be occluded.

The aneurysm may be reduced further in size by deploying gels or using coils.

Where the aneurysm neck is wide, coils or securing glues may be deployed inside

the aneurysm to reduce blood circulation inside the aneurysm. An aneurysm neck

10 may be wide if the ratio of the diameter of the dome of the aneurysm to the width of
the aneurysm neck is less than two.

The stents may be balloon expandable or self-expandable.

The stents may have markers to facilitate precise positioning in the branches. The

15 markers may be placed at the distal and proximal ends of the stents. The markers
may be radiopaque. The markers may be made from gold or platinum.

The stents may be positioned in the branches sequentially.

The stents may be expanded at the same time. Alternatively, the stents may be
expanded sequentially.

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The stent may be tapered towards the distal end of the stent. The stent may have a
trapezoidal longitudinal cross-section. The stent may have proximal end struts that
are elongated relative to the remaining struts.

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The first stent may be positioned partially within the first bifurcation branch such
that a portion of the proximal end of the first stent is not introduced within the first
bifurcation branch.

The second stent may be positioned partially within the second bifurcation branch

30 such that a portion of the proximal end of the second stent is not introduced within
the second bifurcation branch.

A balloon of a balloon catheter may be used to expand the stent during
deployment. The balloon may be tapered such that the proximal end of the stent is
expanded first during deployment. Advantageously, this allows the aneurysm neck

35 to be bridged with greater effectiveness.

The balloon may be made of soft durometer thin nylon or silicon.

The first stent may be expanded by a first balloon and the second stent may be expanded by a second balloon. The first and second balloons may be on a single shaft of a balloon catheter. The stents may be expanded at the same time during deployment.

Additional angioplasty balloon expansion may be used to secure the deployment of the stents.

The stents may be connected by a membrane for obstructing blood circulation to the bifurcation aneurysm. The membrane may comprise at least one layer of an elastomeric polymer. The membrane may comprise receptacles for carrying drugs or reagents for subsequent release after the stents are deployed. The drugs or reagents may include substances that reduce the thrombogenic, inflammatory or smooth muscle cell proliferative response of the vessel to the implantable medical devices. For example, cell inhibitors can be delivered in order to inhibit smooth muscle cells proliferation. In intracranial or some other applications fibrin sealants can be used and delivered to seal aneurysm neck and provide fibroblasts and endothelial cells growth. Specific examples of drugs or reagents may include heparin, phosphorylcholine, albumin, dexamethasone, paclitaxel and vascular endothelial growth factor (VEGF).

In a second aspect, there is provided a method for treating a trifurcation aneurysm, the aneurysm having an aneurysm neck, the method comprising:

positioning a first mechanically expandable device in a first trifurcation branch proximate to the aneurysm neck;
positioning a second mechanically expandable device in a second trifurcation branch proximate to the aneurysm neck;
positioning a third mechanically expandable device in a third trifurcation branch proximate to the aneurysm neck; and
30 expanding the mechanically expandable devices to constrict the aneurysm neck such that blood circulation to the trifurcation aneurysm is reduced.

The first mechanically expandable device may be positioned partially within the first trifurcation branch such that a portion of the proximal end of the first mechanically expandable device is not introduced within the first trifurcation branch.

The second mechanically expandable device may be positioned partially within the second trifurcation branch such that a portion of the proximal end of the second

mechanically expandable device is not introduced within the second trifurcation branch.

The third mechanically expandable device may be positioned partially within the

third trifurcation branch such that a portion of the proximal end of the third

5 mechanically expandable device is not introduced within the third trifurcation branch.

In a third aspect, there is provided a system for treating a bifurcation aneurysm, the aneurysm having an aneurysm neck, the system comprising:

10 a first mechanically expandable device positioned in a first bifurcation branch proximate to the aneurysm neck;

a second mechanically expandable device positioned in a second bifurcation branch proximate to the aneurysm neck; and

15 wherein the mechanically expandable devices are expanded to constrict the aneurysm neck such that blood circulation to the bifurcation aneurysm is reduced.

In a fourth aspect, there is provided a system for treating a trifurcation aneurysm, the aneurysm having an aneurysm neck, the system comprising:

20 a first mechanically expandable device positioned in a first trifurcation branch proximate to the aneurysm neck;

a second mechanically expandable device positioned in a second trifurcation branch proximate to the aneurysm neck;

25 a third mechanically expandable device positioned in a third trifurcation branch proximate to the aneurysm neck; and

wherein the mechanically expandable devices are expanded to constrict the aneurysm neck such that blood circulation to the trifurcation aneurysm is reduced.

30 In a fifth aspect, there is provided a mechanically expandable device for treating a bifurcation or trifurcation aneurysm, the aneurysm having an aneurysm neck, the device comprising:

a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said

35 generally tubular structure expandable from a first position to a second position, and said tubular structure is expanded radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of a

bifurcation or trifurcation branch so as to maintain a fluid pathway through said branch and to constrict the aneurysm neck such that blood circulation to the aneurysm is reduced;

5 wherein a proximal portion of the struts are elongated relative to the remaining struts such that the device is tapered towards its distal end after deployment in the branch.

In a sixth aspect, there is provided a balloon for expanding a mechanically expandable device for treating a bifurcation or trifurcation aneurysm, the balloon 10 being connected to a balloon catheter for inflation, and the device comprising a interconnected struts at its proximal end that are elongated relative to the remaining struts of the device such that the device is tapered towards its distal end after deployment in a bifurcation or trifurcation branch;

15 wherein the balloon is tapered towards its distal end after inflation, and the inflation of the balloon causes the elongated struts of the device to expand at a greater rate than the remaining struts for constricting the aneurysm neck such that blood circulation to the aneurysm is reduced.

20 The balloon may be a first balloon used in combination with a second balloon to expand a second mechanically expandable device in another bifurcation or trifurcation branch. The first balloon and second balloon may be inflated together via a single balloon catheter

Brief Description of the Drawings

25 An example of the invention will now be described with reference to the accompanying drawings, in which:
Figure 1 is a pictorial representation of a bifurcation aneurysm;
Figure 2 is a pictorial representation of a stent deployed in a bifurcation branch;
30 Figure 3 is a pictorial representation of stents deployed in both bifurcation branches;
Figure 4 is a pictorial representation of a reduction of blood circulation to the bifurcation aneurysm when the stents are expanded;
Figure 5 is a pictorial representation of a tapered balloon to deploy the stent in a bifurcation branch;
35 Figure 6 is a pictorial representation of a tapered stent being deployed by a tapered balloon in a bifurcation branch;

Figure 7 is a pictorial representation of tapered stents deployed in both bifurcation branches;

Figure 8 is a pictorial representation of a tapered stent with elongated end struts when deployed;

5 Figure 9 is a pictorial representation of a tapered stent with elongated end struts before deployment;

Figure 10 is a pictorial representation of stents connected by a patch deployed in both bifurcation branches;

10 Figure 11 is a pictorial representation of stents with markers connected by a membrane deployed in both bifurcation branches;

Figure 12 is a pictorial representation of a tapered stent with elongated end struts and a marker before deployment;

Figure 13 is a pictorial representation of tapered stents with markers in both bifurcation branches being expanded by two connected tapered balloons;

15 Figure 14 is a pictorial representation of tapered stents with markers deployed in both bifurcation branches; and

Figure 15 is a pictorial representation of coils deployed in the aneurysm in addition to tapered stents with markers deployed in both bifurcation branches.

20 **Detailed Description of the Drawings**

Referring to Figures 1, a method for treating a bifurcation aneurysm 10 is shown.

The aneurysm 10 has an aneurysm neck 11 where blood passes from a main artery 15 to the aneurysm 10. The aneurysm 10 is located at the end of the main

25 artery 15 where it diverges into two bifurcation branches 12, 13. A first stent 20 is positioned in a first bifurcation branch 12 proximate to the aneurysm neck 11 as shown in Figure 2. Next, a second stent 21 is positioned in a second bifurcation branch 13 proximate to the aneurysm neck 11 as shown in Figure 3. The stents 12, 13 are expanded to constrict the aneurysm neck 11 such that blood circulation to

30 the aneurysm 10 is reduced. In a bifurcation branch 12, 13, the side of the branch wall 12, 13 opposing the aneurysm neck 11 is more rigid relative to the branch wall 12, 13 adjacent to the aneurysm neck 11. Thus, when the stent 20, 30 is expanded, the majority of the expansion force is directed towards the branch wall 12, 13 adjacent to the aneurysm neck 11 which begins to constrict the aneurysm

35 neck 11. Even if the aneurysm neck 11 is partially constricted, blood circulation to the aneurysm 10 is reduced. This eventually leads to the aneurysm 10 drying out from a reduction in blood circulation as shown in Figure 4.

Intracranial stents 20, 30 are designed to be very flexible, and have a low profile (0.033" to 0.034" or even less as crimped onto delivery catheter) and thin wall (0.0027" to 0.0028"). The intracranial stents 20, 30 feature low deployment pressure (3 to 4 atmospheres) and do not necessarily have the highest possible radial strength because there is no need for high strength in intracranial applications. In one example, the stents 20, 30 are made from platinum/iridium/tungsten alloys.

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10 Stents 20, 30 are a generally tubular structure having an exterior surface defined by a plurality of interconnected struts 32 having interstitial spaces there between. The generally tubular structure is expandable from a first position, wherein the stent 20, 30 is sized for intravascular insertion, to a second position, wherein at least a portion of the exterior surface of the stent contacts the vessel wall 12, 13.

15 The expansion of the stent 20, 30 is accommodated by flexing and bending of the interconnected struts 32 throughout the generally tubular structure. It is contemplated that many different stent designs can be produced. A myriad of strut patterns are known for achieving various design goals such as enhancing strength, maximizing the expansion ratio or coverage area, enhancing longitudinal flexibility

20 or longitudinal stability upon expansion. One pattern may be selected over another in an effort to optimize those parameters that are of particular importance for a particular application.

In one example, the stent 20, 30 comprises stent struts 32 of a ring, ring

25 connectors, and end markers 34. The stents 100 are made of multiple circumstantial rings, where the ring connectors connect two or three adjacent rings to hold the rings in place. In another example, a self-expanding stent 20, 30 is made of wires/ribbons. While a self-expanding stent may have many designs, one specific stent 20, 30 has a typical braided pattern with welded ends. The stent 20,

30 is designed such that it is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but is sufficiently stiff and stable radially in an expanded condition to maintain the patency of a body lumen, such as an artery or bifurcation/trifurcation branch 12, 13 when implanted therein. When a tubular stent 20, 30 is fully expanded to its deployed diameter, the latticework of struts 32

35 takes on a shape in which adjacent crests undergo wide separation, and portions of the struts 32 take on a transverse, almost fully lateral orientation relative to the longitudinal axis of the stent 20, 30. Such lateral orientation of a plurality of the

struts 32 enables each fully opened cell to contribute to the firm mechanical support offered by the stent 20, 30 in its fully deployed position, to assure a rigid structure which is highly resistant to recoil of the vessel wall 12, 13 following stent deployment. It bears emphasis, however, that the configuration of this stent structure, while highly desirable, is illustrative only.

Referring to Figures 5 to 9, tapered stents 30, 31 are used to further enhance constriction of the aneurysm neck 11. For the delivery system, a tapered balloon 35 of a balloon catheter 36 expands the tapered stents 30, 31 by inflation, after the stents 30, 31 are placed into position in a respective bifurcation branch 12, 13. At the proximal end of the tapered stents 30, 31 there are elongated struts 33 to provide the tapering effect. The elongated struts 33 expand at a greater rate relative to the non-elongated struts 32. Also, tapered stents 30, 31 after deployment have a profile which conforms to the opening of the bifurcation branch 12, 13 from the main artery 15. Figure 8 depicts a tapered stent 30 in an expanded state, typically when the stent 30 is deployed. Figure 9 depicts the tapered stent 30 in a compressed state, typically during delivery via the balloon catheter 36.

The delivery system includes a guide wire lumen, a balloon inflating lumen, a connector, a balloon catheter shaft, and platinum marker bands on the catheter shaft (not shown). The guide wire lumen is used for introducing a guide wire in a balloon catheter 36, and the balloon inflating lumen is used for inflating the balloon 35 after the stent 20, 30 to be placed reaches its targeted location. The connector is used for separating the guide wire lumen and the balloon inflating lumen. The balloon catheter shaft carries the guide wire lumen and the balloon inflating lumen separately, with a typical length ranging 135 to 170 cm. The ring markers on the catheter shaft are used for showing the start of balloon tapers 35 and the edges of the stent 20, 30.

The balloon 35 is formed of suitable materials such as irradiated polyethylene, polyethylene terephthalate, polyvinylchloride, nylon, and copolymer nylons such as Pebax™. Other polymers may also be used. In order for the stent 20, 30 to remain in place on the balloon 35 during delivery to the desired site within a branch 12, 13, the stent 20, 30 is crimped onto the balloon 35.

In a preferred embodiment, the delivery of the stent 20, 30 is accomplished in the following manner. The stent 20, 30 is first mounted onto the inflatable balloon 35

on the distal extremity of the delivery catheter 36. The stent 20, 30 is mechanically crimped onto the exterior of the folded balloon 35. The catheter/stent assembly is introduced within vasculature through a guiding catheter. A guide wire is disposed across the diseased arterial section and then the catheter/stent assembly is

5 advanced over a guide wire within the branch 12, 13 until the stent 20, 30 reaches the desired position. The balloon 35 of the catheter 36 is expanded, expanding the stent 20, 30 against the branch wall 12, 13. The expanded stent serves to hold open the artery after the catheter is withdrawn. Due to the formation of the stent 20, 30 from an elongated tube, the undulating component of the cylindrical elements of the stent 20, 30 is relatively flat in transverse cross-section, so that when the stent 20, 30 is expanded, the cylindrical elements are pressed against the wall of the branch 12, 13 and as a result do not interfere with the blood flow through the branch 12, 13. The cylindrical elements of the stent 20, 30 which are pressed into the wall of the branch 12, 13 is eventually covered with an endothelial

10 15 cell layer which further minimizes blood flow interference. Furthermore, the closely spaced cylindrical elements at regular intervals provide uniform support for the wall of the branch 12, 13, and consequently are well adopted to take up and hold in place small flaps or dissections in the wall of the branch 12, 13.

20 As described earlier, a stent 20, 30 may be deployed by radial expansion under outwardly directed radial pressure exerted. For example by active inflation of a balloon 35 of a balloon catheter 36 on which the stent 20, 30 is mounted. Another deployment method may rely on the stent 20, 30 being self-expandable. In some instances, passive spring characteristics of a preformed elastic (that is, self-opening) stent 20, 30 serve the purpose. The stent 20, 30 is then expanded to engage the inner lining or inwardly facing surface of the vessel wall 12, 13 with sufficient resilience to allow some contraction but also with sufficient stiffness to largely resist the natural recoil of the vessel wall 12, 13.

25 30 For resilient or self-expanding stents 20, 30, they are deployed without dilation balloons 35. Self-expanding stents 20, 30 are pre-selected according to the diameter of the blood vessel, bifurcation/trifurcation branch 12, 13 or other intended fixation site. While stent deployment requires skill in stent positioning, such deployment does not require the additional skill of carefully dilating a balloon

35 35 to plastically expand the prosthesis to the appropriate diameter. Further, the self-expanding stent 20, 30 remains at least slightly elastically compressed after fixation, and has a restoring force which facilitates acute fixation. By contrast, a

plastically expanded stent 20, 30 must rely on the restoring force of deformed tissue, or on hooks, barbs, or other independent fixation elements.

Referring to Figure 15, in a further example, the aneurysm 10 is reduced further in

5 size by deploying gels or using coils 50. If the aneurysm neck 11 is wide, coils 50 or securing glues (not shown) are deployed inside the aneurysm 10 to reduce blood circulation inside the aneurysm 10. An aneurysm neck 11 can be considered wide if the ratio of the diameter of the dome of the aneurysm 10 to the width of the aneurysm neck 11 is less than two.

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Referring to Figure 10, a pair of stents 20, 21 are joined together by a membrane 25. The membrane 25 obstructs blood circulation to the aneurysm 10. The stents 20, 21 are an open cell design and have a variable profile. Thus in addition to constriction of the aneurysm neck 11 by the stents 20, 21, the presence of the

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membrane 25 also obstructs blood circulation through the aneurysm neck 11 and may hasten the drying out of the aneurysm 10.

In one example, the membrane 25 may comprise one or more layers of an elastomeric polymer. The membrane 25 may comprise a first layer and a second

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layer. Many polymeric materials are suitable for making the layers of the membrane 25. One such material may be elastomeric polyurethane. Typically, one first layer is disposed onto the outer surface of a stent 20, 30.

In certain embodiments, the first layer is an independent membrane to

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mechanically cover and seal the aneurysm 10. In certain embodiments, the first and/or second layers may be made from biodegradable material as a drug or reagent carrier for sustained release.

The intermediate layer may be formed of a material which fuses to the first and

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second layers or attached to the first layer in a different manner. In certain embodiments, the intermediate layer may be merged with the first layer to form a single layer with recessions within the outer surface of the merged layer.

In one embodiment, the second and intermediate layers are made of

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biodegradable material that contains drugs or reagents for immediate or sustained controlled release. After biodegradable material has degraded over time, the

membrane 25 is still in tact to provide vessel support. The second layer may be made from a polymeric material.

The polymeric layers of the membrane 25 may also be made from a material

5 selected from the group consisting of fluoropolymers, polyimides, silicones, polyurethanes, polyurethanes ethers, polyurethane esters, polyurethaneureas and mixtures and copolymers thereof. Biodegradable polymeric materials can also be used.

10 Adhering, laminating, suturing or otherwise bonding fusible polymeric layers may be conducted. The fusion of the polymeric layers may be achieved by various techniques such as heat-sealing, solvent bonding, adhesive bonding or use of coatings.

15 The membrane 25 may further comprise pockets (not shown) serving as receptacles for drugs or reagents so that the drugs or reagents may be delivered into vascular systems. The membrane 25 may cover a part of a stent 20, 30, where the size of the membrane 25 may be varied in accordance with any specific application. In one extreme, the membrane 25 may cover the whole outer surface
20 of a stent 20, 30. Thus, the membrane 25 may be in any shape or size. A drug or reagent can be injected in the form of a gel, liquid or powder into receptacles of the pockets. Alternatively the drug or reagent can be supplied in a powder which has been formed into a solid tablet positioned in the receptacles. Such tablets would gradually dissolve after implantation. The drugs or reagents include substances
25 that reduce the thrombogenic, inflammatory or smooth muscle cell proliferative response of the vessel to the implantable medical devices. For example, cell inhibitors can be delivered in order to inhibit smooth muscle cells proliferation. In intracranial or some other applications fibrin sealants can be used and delivered to seal aneurysm neck and provide fibroblasts and endothelial cells growth. Specific
30 examples of drugs or reagents may include heparin, phosphorylcholine, albumin, dexamethasone, paclitaxel and vascular endothelial growth factor (VEGF).

Figures 11 and 12 show stents 20, 21, 30, 31 with markers 34. The markers 34 improve visibility as they are radiopaque and may be made from gold or platinum.

35 The markers 34 facilitate precise positioning and orientation of the stents 20, 30 during deployment in the branches 12, 13. The markers 34 may be end markers and are usually placed at the distal and proximal ends of the stents 20, 30. The

drawings show a disc shaped marker. However, the shape is not critical so long as the marker 34 can be used to improve visibility of the stent 20, 30. The markers may be center markers that are special type platinum star-shaped markers to assist in precise indication and alignment of the stents 20, 30 in relation to the

5 aneurysm neck 11 and allow further operations with the aneurysm 10. Then, the markers located around the middle of the stent 20, 30. The center markers assist in locating an aneurysm opening during an implantation operation. The center markers can be made of the same material and have the same shape as the end markers.

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Figure 13 shows tapered stents 30, 31 with markers 34 during deployment. The tapered stents 30, 31 are expanded by two balloons 35 via a single balloon catheter 36. After the tapered stents 30, 31 have been expanded the balloons 35 are deflated and the catheter 36 is retracted as shown in Figure 14.

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Although a bifurcation aneurysm 10 has been described, it is envisaged that the present invention may be used for trifurcation aneurysms and the like.

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It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the scope or spirit of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects illustrative and not restrictive.